

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



**ORIGINAL**

Docket No. ORT-1462

IDS/ #01/02  
RECEIVED  
DEC 04 2001  
TECH CENTER 1600/2900

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Loretta ITRI and Peter BOWERS

Serial No.: 09/921,516 Art Unit: N/A

Filed: 1 August 2001 Examiner: N/A

For: **IMPROVED ANTI-VIRAL AND ANTI-TUMOR CHEMOTHERAPY  
BY ADMINISTRATION OF ERYTHROPOIETIN**

I hereby certify that this correspondence is being deposited with the  
United States Postal Service as first class mail in an envelope addressed  
to: Commissioner for Patents, Washington, D.C. 20231 on

25 October 2001

(Date of Deposit)

John W. Wallen, III, Esq.

(Name of applicant, assignee, or Registered Representative)

(Signature)

25 October 2001

(Date of Signature)

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).

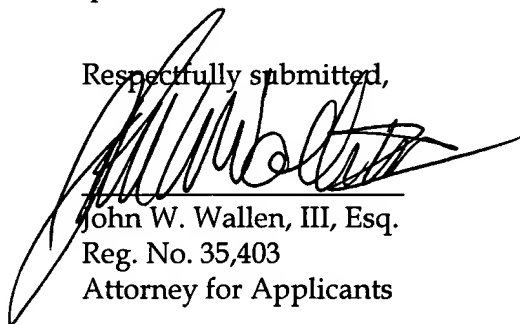
☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1462/JWW. This form is submitted in triplicate.

Respectfully submitted,



John W. Wallen, III, Esq.  
Reg. No. 35,403  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933-7003  
(858) 784-3239  
DATE: 25 October 2001



RECEIVED

DEC 04 2001

TECH CENTER 1600/2900

Page 1 of 4	Application Number	09/921,516
	Filing Date	1 August 2001
	First Named Inventor	ITRI, Loretta
	Group Art Unit	N/A
	Examiner Name	N/A
	Attorney Docket Number	ORT-1462

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	

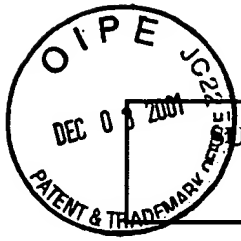
## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>		
		ORTHO-MCNEIL PHARMACEUTICAL, INC.		WO 00/67769	/		
		ORTHO-MCNEIL PHARMACEUTICAL, INC.		WO 00/67776	/		
		ORTHO-MCNEIL PHARMACEUTICAL, INC.		WO 00/61169	/		
		KORKUT, Edib		WO 00/38705	/		
		PERRINE et al.		WO 98/04290	/		
		ELI LILLY AND COMPANY		WO 00/ 32772	/		
		SCHERING CORPORATION		WO 97/16204	/		
		BRIGHAM AND WOMEN'S HOSPITAL		WO 92/08493	/		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		✓ Abrams et al., "Epoetin alfa Improves the Quality of Life (QoL) in HIV+ Patients with Anemia", <i>Blood</i> ; (1998) 92(Sup. 1, Pt. 2):10b (Abs 3020); 40 <sup>th</sup> Annual Meeting of the <i>American Society of Hematology</i> , Miami Beach, FL (Dec. 4-8, 1998).	
		✓ Blanchard et al., "Regulation of the Erythropoietin Gene", <i>Stem Cells</i> (1993) 11(1):1-7.	
		✓ Brugnara et al., "Effects of Subcutaneous Recombinant Human Erythropoietin in Normal Subjects: Development of Decreased Reticulocyte Hemoglobin Content and Iron-Deficient Erythropoiesis", <i>J. Lab. Clin. Med.</i> (1994) 123(5):660-667.	
		✓ David F. Cella, "The Functional Assessment of Cancer Therapy-Anemia (FACT-An) Scale: A New Tool for the Assessment of Outcomes in Cancer Anemia and Fatigue", <i>Seminars in Hematology</i> (1997, July) 34(3, Sup. 2):13-19.	
		✓ David F. Cella, "F.A.C.T. Manual: Functional Assessment of Cancer Therapy (FACT) Scales and the Functional Assessment of HIV Infection (FAHI) Scale Version 3" (September 1, 1994) (prepared with Amy E. Bonomi) Rush-Presbyterian-St. Lukes Medical Center, Chicago, Illinois.	
		✓ Cheung et al., "Comparative Pharmacokinetics, Safety, and Tolerability after Subcutaneous Administration of Recombinant Human Erythropoietin Formulated with Different Stabilizers", <i>Biopharm. Drug Dispos.</i> (2000) 21(6):211-219.	
		✓ Cheung et al., "Pharmacokinetics and Pharmacodynamics of Recombinant Human Erythropoietin After Single and Multiple Subcutaneous Doses to Healthy Subjects", <i>Clinical Pharmacology &amp; Therapeutics</i> (1998) 64(4):412-423.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--



SUBMISSION UNDER MPEP 609 D

Page 2 of 4

Application Number	09/921,516
Filing Date	1 August 2001
First Named Inventor	ITRI, Loretta

TECH CENTER 1600/2900

DEC 04 2001

RECEIVED

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

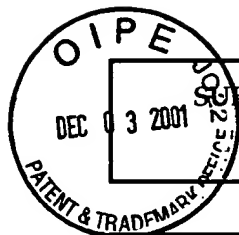
Examiner Initials*	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T2
		✓ <u>Damon</u> et al., "High-Dose Chemotherapy and Hematopoietic Stem Cell Rescue for Breast Cancer: Experience in California", <i>Biology of Blood and Marrow Transplantation</i> (2000) 6(5):496-505.	
		✓ <u>Danna</u> et al., "Erythropoietin Therapy for the Anemia Associated with AIDS and AIDS Therapy and Cancer", <i>Erythropoietin in Clinical Applications: An International Perspective</i> , (Marc B. Garnick, Ed.; Marcel Dekker, Pub.) Jan. 1990, Ch. 11, 301-324.	
		✓ <u>Davis</u> et al., "Interferon alfa-2b Alone or in Combination with Ribavirin for the Treatment of Relapse of Chronic Hepatitis C", <i>New England Journal of Medicine</i> (1998) 339(21):1493-1499.	
		✓ <u>Davis</u> et al., "Retreatment of Relapse After Interferon Therapy for Chronic Hepatitis C: An International Randomized Controlled Trial of Interferon Plus Ribavirin vs. Interferon Alone", <i>Hepatology</i> (1997) 26(4):247A (Abstract only)..	
		✓ <u>de Andrade</u> et al., "Baseline Hemoglobin as a Predictor of Risk of Transfusion and Response to Epoetin alfa in Orthopedic Surgery Patients", <i>American Journal of Orthopedics</i> (Aug. 1996) 25(8):533-542.	
		✓ George D. Demetri, "Evidence-Based Use of Hematopoietic Cytokines in Clinical Oncology", <i>Clinical Applications of Cytokines and Growth Factors</i> , Vol. 80, (J. R. Wingard: Ed.; Kluwer Academic Publishers), Jan. 1999, Ch. 6, 137-149.	
		✓ <u>Demetri</u> et al., "Quality of Life Benefit in Chemotherapy Patients Treated with Epoetin alfa is Independent of Disease Response or Tumor Type: Results from a Prospective Community Oncology Study", <i>J. Clin. Oncol.</i> (1998) 16(10):3412-3425.	
		✓ <u>Dieterich</u> et al., "Interferon- $\alpha$ (IFN- $\alpha$ ) and Ribavirin (RBV) Therapy for Hepatitis C (HCV) in HIV Co-Infected Patients", (Abstract and Poster Presentation for American Society for Microbiology) <i>Proceedings of the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy</i> , (26-29 Sep. 1999) San Francisco, CA.	
		✓ <u>Donahue</u> et al., "Suppression of In Vitro Haematopoiesis Following Human Immunodeficiency Virus Infection", <i>Nature (London)</i> (1987, Mar.) 326(6109):200-203.	
		✓ <u>Dusheiko</u> et al., "Ribavirin Treatment for Patients with Chronic Hepatitis C: Results of a Placebo-Controlled Study", <i>J. Hepatol.</i> (1996) 25(5):591-598.	
		✓ <u>Escribano</u> et al., "Expression of the c-kit (CD117) Molecule in Normal and Malignant Hematopoiesis", <i>Leukemia and Lymphoma</i> (1998) 30(5/6):459-466.	
		✓ <u>Fiel</u> et al., "Increased Hepatic Iron Deposition Resulting from Treatment of Chronic Hepatitis C with Ribavirin", <i>Am. J. Clin. Pathol.</i> (2000) 113(1):35-39.	
		✓ <u>Galson</u> et al., "Cis Elements that Regulate the Erythropoietin Gene", <i>Ann. N. Y. Acad. Sci.</i> (1994) 718:21-30.	
		✓ D. Gillings and G. Koch, "The Application of the Principle of Intention-to-Treat in the Analysis of Clinical Trials", <i>Drug information Journal</i> (1991) 25:411-424.	
		✓ John Glaspy, "The Impact of Epoetin alfa on Quality of Life During Cancer Chemotherapy: A Fresh Look at an Old Problem", <i>Seminars in Hematology</i> (1997, July) 34(3 Sup. 2):20-26.	
		✓ <u>Glaspy</u> et al., "Impact of Therapy with Epoetin alfa on Clinical Outcomes in Patients with Non-Myeloid Malignancies during Cancer Chemotherapy in Community Oncology Practice", <i>J. Clin. Oncol.</i> (1997, March) 15(3):1218-1234.	
		✓ Mark A. Goldberg, "Perioperative Epoetin alfa Increases Red Blood Cell Mass and Reduces Exposure to Transfusions: Results of Randomized Clinical Trials", <i>Semin. Hematol.</i> (1997, July) 34(3 Sup. 2):41-47.	
		✓ <u>Goldberg</u> et al., "A Safety and Efficacy Comparison Study of Two Dosing Regimens of Epoetin Alfa in Patients Undergoing Major Orthopedic Surgery", <i>The American Journal of Orthopedics</i> (1996, August) 544-552.	
		✓ Jerome E. Groopman and Loretta M. Itri, "Chemotherapy-Induced Anemia in Adults: Incidence and Treatment", <i>J. Natl. Cancer Inst.</i> (1999, October) 91(19):1616-1634.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

RECEIVED

DEC 04 2001

TECH CENTER 1600/2900



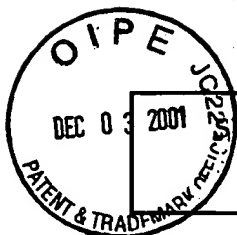
SUBMISSION UNDER MPEP 609 D		Application Number	09/921,516
Page 3 of 4		Filing Date	1 August 2001
		First Named Inventor	ITRI, Loretta

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T2
		✓ <u>Groopman</u> et al., "Hematopoietic Growth Factors in AIDS", <i>Seminars in Oncology</i> (1992, August) 19(4):408-414.	
		✓ J.E. Groopman, "Antiretroviral Therapy and Immunomodulators in Patients with AIDS", <i>American Journal of Medicine</i> (April, 1991) 90(4A):18S-21S.	
		✓ Jerome E. Groopman, "Retroviral Infection and Hemopoiesis", <i>Molecular Control of Haemopoiesis</i> , Vol. 148, (G. Bock and J. Marsh: Eds.; John Wiley & Sons, Ltd., Chichester, United Kingdom: Pub.) Ciba Foundation Symposium, May 2-4, 1989, London, United Kingdom (1990, Jan) 148:173-185.	
		✓ <u>Groopman</u> et al., "Hematopoietic Growth Factors: Biology and Clinical Applications", <i>N. Engl. J. Med.</i> (1989) 321(21):1449-1459.	
		✓ David H. Henry, "Supplemental Iron: A Key to Optimizing the Response of Cancer-Related Anemia to rHuEPO?", <i>Oncologist</i> (1998) 3(4):275-278.	
		✓ David H. Henry, "Epoetin alfa and High-Dose Chemotherapy", <i>Seminars in Oncology</i> (1998, June) 25(3, Sup. 7):54-57.	
		✓ David H. Henry, "Experience with Epoetin alfa and Acquired Immunodeficiency Syndrome Anemia", <i>Seminars in Oncology</i> (1998, June) 25(3, Sup. 7):64-68.	
		✓ <u>Henry</u> et al., "Recombinant Human Erythropoietin in the Treatment of Anemia Associated with Human Immunodeficiency Virus (HIV) Infection and Zidovudine Therapy", <i>Annals of Internal Medicine</i> (1992, November) 117(9):739-748.	
		✓ <u>Laso</u> et al., "Alterations in Tumor Necrosis Factor- $\alpha$ , Interferon- $\gamma$ , and Interleukin-6 Production by Natural Killer Cell-Enriched Peripheral Blood Mononuclear Cells in Chronic Alcoholism: Relationship with Liver Disease and Ethanol Intake", <i>Alcohol.: Clin. Exp. Res.</i> (1997) 21(7):1226-1231.	
		✓ <u>McHutchinson</u> et al., "Interferon alfa-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis as Initial Treatment for Chronic Hepatitis", <i>New England Journal of Medicine</i> (1998, November) 339(21):1485-92.	
		✓ R. T. Means and S. B. Krantz., "Inhibition of Human Erythroid Colony-Forming Units by $\gamma$ -Interferon Can Be Corrected by Recombinant Human Erythropoietin", <i>Blood</i> (1991, November) 78(10):1564-2567.	
		✓ <u>Molina</u> et al., "Human Immunodeficiency Virus Does Not Induce Interleukin-1, Interleukin-6, or Tumor Necrosis Factor in Mononuclear Cells", <i>J. Virology</i> (1990, June) 64(6):2901-2906.	
		✓ <u>Pecherstorfer</u> et al., "Erythropoietin in Multiple Myeloma", <i>Deutsche Medizinische Wochenschrift</i> (July, 1990) 115(28-29):1096-1099. (translated)	
		✓ David L. Porter and Mark A. Goldberg, "Regulation of Erythropoietin Production", <i>Exp. Hematol. (Charlottesville, VA)</i> (1993) 21(3):399-404.	
		✓ <u>Reichard</u> et al., "Randomized Double-Blind, Placebo-Controlled Trial of Interferon $\alpha$ -2b with and without Ribavirin for Chronic Hepatitis C", <i>Lancet</i> (1998, Jan.) 351:83-87.	
		✓ <u>Reichard</u> et al., "Therapy of Hepatitis C: Alpha Interferon and Ribavirin", <i>Hepatology</i> (1997, September) 26(3 Sup. 1):108S-111S.	
		✓ <u>Revicki</u> et al., "Recombinant Human Erythropoietin and Health-Related Quality of Life of AIDS Patients with Anemia", <i>J. Acq. Immune. Defic. Syn.</i> (1994) 7(5):474-484.	
		✓ <u>San Miguel</u> et al., "Treatment of Multiple Myeloma", <i>Hematologica</i> (1999) 84(1):36-58.	
		✓ <u>Schalm</u> et al., "Ribavirin Enhances the Efficacy but not the Adverse Effects of Interferon in Chronic Hepatitis C", <i>J. Hepatol.</i> (1997) 26(5):961-966.	
		✓ <u>Schvarcz</u> et al., "Combination Treatment with Interferon alfa-2b and Ribavirin for Chronic Hepatitis C in Patients Who Have Failed to Achieve Sustained Response to Interferon Alone: Swedish Experience", <i>J. Hepatol.</i> (1995) 23(Sup. 2):17-21.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--





SUBMISSION UNDER MPEP 609 D

Page 4 of 4

Application Number 09/921,516

Filing Date 1 August 2001

First Named Inventor ITRI, Loretta

TECH CENTER 1600/2900

DEC 04 2001

RECEIVED

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		<u>Silvestris</u> et al., "Immunomodulation of T and B Cell Functions in Multiple Myeloma Patients Treated with Combined Erythropoietin and $\alpha$ -Interferon Therapy", <i>International Journal of Clinical and Laboratory Research</i> (1995) 25(2):79-83.	
		<u>Stowell</u> et al., "An Open-Label, Randomized Study to Compare the Safety and Efficacy of Perioperative Epoetin alfa with Preoperative Autologous Blood Donation in Total Joint Arthroplasty", <i>Orthopedics</i> (Jan. 1999) 22(1, Supp.):s105-s112.	
		<u>Svensson</u> et al., "Determination of Ribavirin in Serum Using Highly Selective Solid-Phase Extraction and High-Performance Liquid Chromatography", <i>Therapeutic Drug Monitoring</i> (2000) 22(2): 215-218.	
		Karen Weiss, "Safety Profile of Interferon- $\gamma$ Therapy", <i>Semin. Oncol.</i> (1998, February) 25(1 Sup. 1):9-13.	
		<u>Weisz</u> et al., "Erythropoietin Use for Ribavirin/Interferon Induced Anemia in Patients with Hepatitis C", (Abstract and Poster Presentation) 38 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, (24-27 Sep. 1998) San Diego, CA.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--